CLAIM AMENDMENTS

1 (Currently Amended). A method for detecting prion disease in animal carcasses utilizing antibodies specific for PrP^{SC} comprising the steps of:

(a) terminating an animal;

(b) removing a biological sample from the terminated animal;

(c) homogenizing the sample with an analyte-extracting buffer to form a homogenate;

(d) treating the homogenate with immobilized proteinase-K to remove interfering constituents;

(e) assaying the enzyme-treated homogenate for ~~an analyte indicative of the disease~~ PrP^{SC} by using a pair of antibodies specific to the analyte;

(f) obtaining a test result for the analyte in the sample; and

(g) correlating the test result to the animal so the carcass having a positive ~~or~~ test result may be separated from a carcass having a negative test result ~~may be removed~~.

2 (Original). The method of claim 1 wherein the analyte causes transmissible spongiform encephalopathy.

3 (Original). The method of claim 1 wherein the test result is produced within from about 5 to about 10 minutes after commencing the assaying step.

4 (Currently Amended). The method of claim 1 wherein the homogenizing step comprises homogenizing the sample with a sufficient quantity of the buffer to extract the ~~prion protein~~ analyte from the sample.

5 (Original). The method of claim 4 wherein the buffer is aqueous and comprises at least one emulsifier or surfactant, casein, at least one polysaccharide, and albumin.

6 (Currently Amended). The method of claim 5 wherein the at least one emulsifier or surfactant is selected from the group consisting of octoxynol, nonoxynol, polyglycol ether, polyoxythylene (10) isooctylphenyl ether, sodium dodecyl sulfate (SDS), and sodium deoxycholate.

7 (Currently Amended). The method of claim 5 wherein the at least one polysaccharide is selected from the group consisting of sucrose, mannose, trehalose, and maltose.

8 (Original). The method of claim 1 wherein the buffer has an ionic strength of from about 200 to about 400 mM.

9 (Original). The method of claim 1 wherein the assaying step is conducted in a test device comprising the immobilized proteinase-K and a lateral flow membrane for immunochromatographic analysis of the enzyme-treated homogenate.

10 (Original). The method of claim 9 wherein the step of correlating a test result to the animal includes attaching at least a portion of the test device to a part of the animal.

11 (Currently Amended). The method of claim 10 further comprising prior to removing the biological sample, the step of attaching a test device holder to the animal for subsequent fastening thereto of ~~the~~ at least a portion of the test device.

12 (Original). The method of claim 10 wherein the correlating step comprises separating the diseased carcass from nondiseased carcasses.

13 (Original). The method of claim 1 further comprising processing nondiseased animals for use as food for humans and as ingredients for animal feed.

14 (Currently Amended). A method for ~~diagnosing~~ detecting a prion disease[[s]] in humans or animals, comprising:

(a) obtaining a biological sample from a vertebrate;

(b) homogenizing the sample with a buffer to form a homogenate containing extracted prion protein;

(c) introducing the homogenized sample into a lateral flow device having immobilized proteinase-K for *in situ* digestion of interfering constituents and a pair of antibodies specific ~~to the prion protein analyte for binding to the analyte~~ for PrP^{SC};

(d) obtaining a test result for the ~~prion protein analyte~~ PrP^{SC}; and

(e) correlating the test result to the vertebrate from whom the biological sample was obtained.

15 (Original). The method of claim 14 wherein the pathogenic prion protein being analyzed causes a condition selected from the group consisting of spongiform encephalopathy in bovine, sheep, and goats and scrapie in sheep and goat; transmissible mink encephalopathy (TME) in mink; chronic waste disease (CWD) in mule deer and elk; bovine spongiform encephalopathy (BSE) in cattle; feline spongiform in cats; and kuru, Creutzfeldt-Jakob-disease (CJD), German-Straussler-Scheinker syndrome (GSS), and fatal familial insomnia (FFI) in humans.

16 (Currently Amended). The method of claim 14 wherein the biological sample is selected from the group consisting of blood, serum, plasma, saliva, urine, and cerebral spinal fluid.

17 (Original). The method of claim 14 wherein the biological sample is blood.

18 (Original). The method of claim 14 wherein the proteinase K is present in the test device in an amount ranging from about 30 micrograms to about 400 micrograms.

19 (Original). The method of claim 14 wherein the test result is obtained within from about 5 to about 10 minutes from the time of introducing the sample into the device.

20 (Original). The method of claim 14 wherein the homogenizing step comprises homogenizing the sample with a sufficient quantity of the buffer to extract substantially all the prion protein from the sample.

21 (Original). The method of claim 14 wherein the buffer comprises at least one emulsifier or surfactant, casein, at least one polysaccharide, albumin, and a sufficient quantity of water to form a mixture.

22 (Currently Amended). The method of claim 20 wherein the at least one emulsifier or surfactant is selected from the group consisting of octoxynol, nonoxynol, polyglycol ether, polyoxythylene (10) isooctylphenyl ether, sodium dodecyl sulfate (SDS), and sodium deoxycholate.

23 (Currently Amended). The method of claim 20 wherein the at least one polysaccharide is selected from the group consisting of sucrose, mannose, trehalose, and maltose.

24 (Original). The method of claim 14 wherein the buffer has an ionic strength of from about 200 to about 400 mM.

25 (Currently Amended). A method for detecting ~~or measuring the concentration of~~ an infectious prion protein in foodstuff comprising the steps of:

(a) obtaining a sample of foodstuff;

(b) homogenizing the foodstuff with a buffer to form a homogenate;

(c) treating the homogenate with proteinase-K to digest nonpathogenic prion protein;

(d) assaying the enzyme-treated homogenate for ~~a prion protein indicative of a prion disease~~ PrP^{SC} by using an immunochromatographic technique;

(f) obtaining a test result from the assay; and

(g) correlating the test result to the animal feed.

26 (Original). The method of claim 25 wherein the prion protein being analyzed causes spongiform encephalopathy and Creutzfeld-Jakob-disease.

27 (Original). The method of claim 25 wherein the proteinase-K in the enzyme-treating step is immobilized on a support.

28 (Currently Amended). The method of claim 27 wherein the assaying step is conducted on a test device having:

(a) a porous membrane through which the sample substantially free of nonpathogenic prion protein migrates by capillary action, the membrane being in fluid communication with the proteinase support; and

(b) a pair of antibodies specific to the ~~pathogenic prion protein~~ PrP^{SC}, one of the antibodies being immobilized on the membrane; and the other of the antibodies being labeled such that the labeled antibodies bind with the ~~pathogenic prion protein~~ PrP^{SC} and migrate toward the immobilized antibody.

29 (Original). The method of claim 25 wherein the proteinase-K is immobilized on a support selected from latex beads, rod-shaped bodies coated with latex, micro- or nanoparticles, and a porous membrane pad.

30 (Original). The method of claim 27 wherein the amount of proteinase K immobilized on the support is sufficient to substantially digest all protein in the sample.

31 (Original). The method of claim 30 wherein the amount of enzyme on the support ranges from about 30 micrograms to about 400 micrograms.

32 (Original). The method of claim 25 wherein the labeled antibody has a colored label.

33 (Original). The method of claim 27 wherein the buffer in the homogenizing step comprises at least one emulsifier or surfactant, casein, at least one sugar, salt, albumin, and a sufficient quantity of water to form a mixture.

34 (Original). The method of claim 25 wherein the homogenizing step comprises homogenizing the sample with the buffer in a weight(mg)/volume(ml) ratio ranging from about 5:1000 to about 400:1000.